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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,413	04/15/2004	Rafael Gomez	P27-045	9356
7590		10/09/2007		
R. Neil Sudol 714 Colorado Avenue Bridgeport, CT 06605-1601			EXAMINER BEISNER, WILLIAM H	
			ART UNIT 1797	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/825,413

**Applicant(s)**

GOMEZ ET AL.

**Examiner**

William H. Beisner

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 4/15/07; 3/2/07.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statements filed 4/15/2004 and 3/02/2007 have been considered and made of record.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20-24 are indefinite because it is not clear if the “retention means” recited in claim 20 is different from the “retention device” recited in claim 19. Clarification and/or correction is requested. Note claims 21-24 use both the language “retention means” and “retention device”.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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*Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-4, 7-21 and 24-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,716,620. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1-4, 7-21 and 24-27 are generic to all that is recited in claims 1-20 of U.S. Patent No. 6,716,620. That is, claims 1-20 of U.S. Patent No. 6,716,620 fall entirely within the scope of claims 1-4, 7-21 and 24-27 or, in other words, claims 1-4, 7-21 and 24-27 are anticipated by claims 1-20 of U.S. Patent No. 6,716,620.

6. Claims 5, 6, 22 and 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,716,620 in view of *Miles et al.*(US 6,576,459).

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Claims 1-20 of U.S. Patent No. 6,716,620 encompass a device that is substantially the same as that instantly recited in instant claims 5, 6, 22 and 23.

Claims 5, 6, 22 and 23 differ by reciting that the retention device includes electrodes for generating a non-uniform electric field to retain the microorganisms.

The reference of Miles et al. discloses that it is known in the art to collect desired analytes on carrier beads within a non-uniform electric field (See the Figure and column 5, lines 27-52).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a non-uniform electric field retention device in the system of the primary reference for the known and expected result of providing an alternative means recognized in the art for retaining a desired analyte to be detected within a microfluidic device. Note the field is capable of being applied periodically.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 2, 8-12, 14, 15, 18-21, 24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Wilding et al.(US 5,726,026).

The reference of Sheppard, Jr. et al. discloses a biosensor device which includes a microfabricated substrate that includes a detection chamber (See column 3, lines 5-38; column 15, lines 48-55) for entraining living microorganisms, the detection chamber includes an inlet and outlet and a retention or concentration element for retaining microorganisms while permitting the passage through the detection chamber of contaminant materials in a fluid stream (See column 18, lines 31-65). The device also includes measurement means relative to the detection chamber for detection of cell viability, physiology or metabolism. The reference discloses the use of electrodes within the detection chamber for measuring AC impedance changes within the detection chamber (See column 25, lines 15-36). The reference also discloses

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the use of temperature control elements in combination with the substrate and chambers (See column 25, lines 37-67).

While the reference of Sheppard, Jr. et al. discloses a chamber volume of “from about 5 $\mu$ L to about 1000 $\mu$ L” (See column 15, lines 53-54), claims 1 and 19 recite chamber volumes of 1picoliter to 1microliter.

The reference of Wilding et al. discloses that microfabricated devices can include chambers of 0.01 to 100microliters (See column 16, lines 9-12).

In view of this teaching, manufacture and use of microfabricated devices with chambers within the claimed range would have been obvious to one of ordinary skill in the art based merely on the known and expected result of minimizing the amounts of sample and reagents required to be used in the system.

With respect to claims 2, 8 and 9, the chamber of the reference of Shepard is capable of confining 1-1000 microorganisms and the disclosed heating system would be capable of maintaining the chamber within 0.1 deg. C of a desired temperature and heating the chambers for several hours.

With respect to claims 10, 11 and 12, the electrodes of the device of Shepard are capable of sampling at the frequencies recited in claims 10 and 11 and generating impedance as a function of frequency.

With respect to claims 14 and 15, the reference of Shepard includes data processors and/or controllers that are structurally capable of detection and comparison of impedance over time (See columns 27-28).

With respect to claims 18 and 27, the electrodes are mounted within the detection chamber so as to be capable of detecting AC impedance changes (See column 25, lines 15-36).

With respect to claims 20 and 24, the reference of Shepard discloses a physical retention device (See column 18, lines 31-65).

Claim 21 differs by reciting that the retention means for the system includes a magnetic field generating element.

The reference of Wilding et al. discloses that it is known in the art to employ magnetic particles and a magnetic field generating means to selectively concentrate a desired sample in a biochip device (See column 9, lines 25-49).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system of the primary reference with magnetic particles and a magnetic field generating means for the known and expected result of providing an alternative means recognized in the art to achieve the same result, selectively concentrate the microorganisms to be detected in a detection chamber.

11. Claims 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Wilding et al.(US 5,726,026) and Feldberg (US 5,824,494).

The combination of the references of Sheppard, Jr. et al. and Wilding et al. has been discussed above.

With respect to the claimed use of a range of frequencies of claims 10-12, 14 and 15, the reference of Feldberg discloses that it is known in the art to measure a component part of the



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impedance of the sample over a range of frequencies (See column 11, lines 45, to column 12, line 38).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ impedance component analysis over a range of frequencies in the system of the device of Shepard et al. for the known and expected result of increasing the sensitivity of the detection system.

With respect to the use of a phasor as recited in claims 13 and 16, while the reference of Feldberg discloses the use of Warburg's impedance as a preferred embodiment, the reference also states that other impedance components can be used and thus would have been within the purview of one of ordinary skill in the art.

12. Claims 17 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Wilding et al.(US 5,726,026) and Hintsche et al. (US 5,670,031).

The combination of the references of Sheppard, Jr. et al. and Wilding et al. has been discussed above.

The above claims differ by reciting the use of interdigitized electrodes.

The reference of Hintsche et al. discloses that the use of interdigitized electrodes in a biosensor device provides an amplification effect (See column 4, line 63, to column 5, line 6).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide the system of the

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modified primary reference with interdigitized electrodes for the known and expected advantage disclosed by the reference of Hintsche et al.

13. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Wilding et al.(US 5,726,026) and Miles et al.(US 6,576,459).

The combination of the references of Sheppard, Jr. et al. and Wilding et al. has been discussed above.

Claims 22 and 23 differ by reciting that the retention device includes electrodes for generating a non-uniform electric field to retain the microorganisms.

The reference of Miles et al. discloses that it is known in the art to collect desired analytes on carrier beads within a non-uniform electric field (See the Figure and column 5, lines 27-52).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a non-uniform electric field retention device in the system of the primary reference for the known and expected result of providing an alternative means recognized in the art for retaining a desired analyte to be detected within a microfluidic device. Note the field is capable of being applied periodically.

14. Claims 5, 6, 22 and 23 are rejected under 35 U.S.C. 103(a) as being obvious over Bashir et al.(US 6,716,620) in view of Miles et al.(US 6,576,459).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The reference of Bashir et al. discloses a device that is substantially the same as that instant claimed. The reference discloses a collection chamber (34) with a microchannel inlet and outlet (See Figure 19). The reference discloses a retention structure that include means for generating a magnetic field (See column 28, line 53, to column 29, line 43).

With respect to claims 5, 6, 22 and 23, while the reference discloses a magnetic retention device in the collection chamber, the instant claims differ by reciting the use of a device for generating a non-uniform electric field.

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The reference of Miles et al. discloses that it is known in the art to collect desired analytes on carrier beads within a non-uniform electric field (See the Figure and column 5, lines 27-52).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a non-uniform electric field retention device in the system of the primary reference for the known and expected result of providing an alternative means recognized in the art for retaining a desired analyte to be detected within a microfluidic device.

### ***Conclusion***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/  
Primary Examiner  
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WHB